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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,228	10/28/2005	David W Morris	PP23370.0003/20366-036US1	4557

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/539,228	**Applicant(s)** MORRIS ET AL.	
	Examiner ANNE L. HOLLERAN	**Art Unit** 1643	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 17 February 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *02 March 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because: Claims 32-34, 51, 78, 82-87, 89, 90, 93 and 94 are pending. Claims 32-34 are withdrawn from consideration. Claims 51, 78, 82-87, 89, 90, 93 and 94 are rejected, and have not been amended by the response filed 2/17/2010.
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Claims 51, 78, 82-87, 89, 90, 93 and 94 remain rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. The claims(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connnected, to make and/or use the invention.

The specification does not reasonably provide enablement for methods of diagnosing any and all cancers, or diagnosing colon, breast or prostate cancer, comprising the active steps of differential detection of expression of a gene which expresses a nucleic acid comprising SEQ ID NO: 777 in a patient sample, comprising colon, breast or prostate tissue; comprising detecting evidence of differential expression of myosin I gene which expresses a ucleic acid comprising SEQ ID NO: 777 in a patient sample; or diagnosing colon, breast or prostate cancer in a patient comprising detecting the amount of a duplex formed between a polynucleotide that hybridizes under conditions recited in claim 94 to a nucleotide sequence comprising SEQ ID NO: 777, when contacted with nucleic acids of a patient colon, breast or prostate sample.

Applicants state that the aplcation provides a sufficient link between the claimed SEQ ID NO: 777 and diagnosis of cancer to enable those skilled in the art to practice the invention as claimed. Applicants state that the specification demonstrates a linke beteween use of oncogenic retroviruses for identification of host cancer related sequences such as the claimed SEQ ID NO: 777. However, in response, the claims are not drawn to identification of cancer related sequences, but instead are drawn to diagnosing any and all cancer (claim 51) or diagnosing colon, breast or prostate cancer (claims 78, 82-87, 89, 90, 93 and 94) comprising the detection of SEQ ID NO: 777, or a protein encoded by SEQ ID NO: 777, or to expression of a gene that encodes SEQ ID NO: 777, or the detection of a polynucleotide that hybridizes to SEQ ID NO: 777 (under specific conditions stated in claim 94).

Applicants state that the teachings of Berns further supports enablement of the claimed inventions, because Berns teaches that protooncogenes identified by provirus tagging may be gene expressed in any stage of cancer. Thus, applicants state, the claimed invention may be used for the early detection of cancer.

This is not found persuasive because Berns teaches that proviral tagging is a method to find candidate genes that is involved in tumorigenesis ("genes that can contribute to tumorigenesis"; page 11). However, discovering a gene that may or may not have a role in tumorigenesis is not sufficient experimental evidence that a particular gene, such as for example the gene encoding the nucleic acid of SEQ ID NO: 777, can be used as a diagnostic for any and all cancers, or as a diagnositic for particular cancers (colong, breast or prostate cancer). The specification does not provide any experimental evidence showing that measurement of this particular gene's expression is useful for detecting cancer. Furthermore, there is no post-filing date evidence found by the examiner, nor provided by applicants, demonstrating that measurement of the expression of this gene can be used in a method of detecting cancer.